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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,801	05/30/2001	John W. Cherwonogrodzky	3929-3	5677

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,801	CHERWONOGRODZKY, JOHN W.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-65,67-80,83-86 and 88-90* is/are pending in the application.

4a) Of the above claim(s) *83-86 and 88-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-65 and 67-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Upon further consideration the finality of the Final Office action mailed March 29, 2005 has been withdrawn. Claims 1-62, 66, 81-82, 87 and 91 have been cancelled. Claims 63, 76 and 80 have been amended. Claims 83-86 and 88-90 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 63-65, 67-80 are under examination. A non-final action is disclosed below:

Rejections Withdrawn

2. In view of Applicant's amendment and response the following rejections are withdrawn:

a) rejection was claims 63-65, 67-73, 75-76 and 78-79 under 35 U.S.C. 102(b), pages 3-5, paragraph 4.

b) rejection was claims 63-67 and 72 under 35 U.S.C. 102(b), pages 6-7, paragraph 5.

c) rejection was claims 63-68, 72, 74, 76 and 78-79 under 35 U.S.C. 102(b), pages 8-9, paragraph 6.

d) rejection was claims 63-65, 67-68, 73 and 78-81 under 35 U.S.C. 102(b), pages 9-11, paragraph 7.

e) rejection was claims 63-64, 67, 68, 70-72, 77-78 and 82under 35 U.S.C. 102(b), pages 11-12, paragraph 8.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

3. Claims 63-65 and 67-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

The claims recite, "...said antigenic composition being characterized by a reduction of antigenic activity of less than about 20% as measured by ELISA...". This claim limitation is not supported by the original disclosure. The specification discloses antigenic compositions that have antigenic activity of 10-20% in the ELISA reading (see page 16). Applicant has failed to direct the Examiner as to where in the instant specification the support for this claim limitation is specifically shown or implied. The Examiner has reviewed the instant specification and has failed to find the support for the amendment. Applicant is required to cancel the new matter in the reply to this Office Action.

Written Description

4. Claims 63-65 and 67-80 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 63-65 and 67-80 are drawn to an antigenic composition for detecting anti-aflatoxin antibodies from a sample of a test subject said composition comprising a fungal or yeast cell culture supernatant containing fungal or yeast components shed into the supernatant during culturing; said antigenic composition being characterized by a reduction of antigenic activity of less than 20% as measured by ELISA after treatment with protease in 0.25M TRIS buffer at pH 7.2.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus or alternatively describe a representative member of the claimed genus which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus. This, description would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. What kind of fungal or yeast components are these? Do these fungal or yeast components have specific characteristics or properties?

The instant specification has not adequately described the claimed antigenic compositions. It is unclear as to what components are contained in the claimed compositions.

The instant specification discloses culture supernatant antigens were prepared and test antigen sensitivities were evaluated for DNAse, RNAse or protease (page 8). The specification discloses that the culture antigens were tested using Male CD1 mice (page 9). The specification refers to the test antigen as "killed fungal or yeast cellular material" (page 9). What constitutes the "fungal or yeast cellular material"? The instant specification does not disclose that aflatoxins are contained in the claimed compositions. The specification merely discloses that aflatoxins were purchased and used as controls (page 9).

To adequately describe the genus of antigenic compositions, one skilled in the art must describe components that are contained in the compositions. The specification has not provided written description for the claimed compositions. A description of what components used to formulate the composition might reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

The claims (dependent claims 78 and 79) require that the claimed compositions are used as vaccines. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity. The specification merely discloses that the claimed antigenic compositions can be used to elicit antibodies. See pages 17-30 of the instant specification. The specification does not provide substantive evidence that the

vaccines of invention are capable of inducing protective immunity. No challenge studies were preformed. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. It should be noted that an antigen's ability to produce antibodies is very different from the antigen's ability to provide protective immunity. This is evidenced by Boslego et al (*Vaccines and Immunotherapy, Pergaman Press, 1991, Chapter 17)* wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the

written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. *The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph* 1, "Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104). Moreover, because the claims encompass a genus of compositions, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of compositions, the skilled artisan could not immediately recognize or distinguish members of the claimed antigenic compositions or vaccine compositions comprising the antigenic compositions would provide prophylactic efficacy against infection or disease.

In view of the above, the instant specification fails to meet the written description requirement as set forth under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 63-65 and 67-80 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what is contained in the antigenic compositions. What is contained in the fungal or yeast supernatants? Clarification and/or correction is required.

6. Claims 63-65 and 67-80 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no lower limit set forth in the range recited in the claims. Does less than 20% include 0%? Clarification and/or correction is required.

Status of Claims

7. No claims are allowed.

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272–1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (571) 272-8300.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 14, 2006

NITA MINNIFIELD
PRIMARY EXAMINER